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11/05/2001

Christian Rosenmund

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08/22/2006

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EXAMINER

ULM, JOHN D

ART UNIT

PAPER NUMBER

1649

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |   |  |
|------------------------------|--------------------------------------|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/807,499 | <b>Applicant(s)</b><br>ROSENMUND ET AL. |  |
|                              | <b>Examiner</b><br>John D. Ulm       | <b>Art Unit</b><br>1649                 |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 2,5-35 and 37 is/are pending in the application.  
     4a) Of the above claim(s) 18-20 and 24-33 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2,6-8,10-14 and 17 is/are allowed.
- 6) ☒ Claim(s) 9,15,16,22,23,34 and 35 is/are rejected.
- 7) ☒ Claim(s) 5,21 and 37 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/5/01 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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1) Claims 2, 5 to 35 and 37 are pending in the instant application. Claims 2, 5 to 8, 10, 17, 21, 34 and 37 have been amended claims 1, 3 and 4 have been canceled as requested by Applicant in the correspondence filed 10 February of 2006.

2) Claims 18 to 20 and 24 to 33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 25 October of 2004. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement with respect to these claims, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5) A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10 February of 2006 has been entered.

6) The instant specification does not comply with 37 C.F.R. § 1.77, which requires that:

(a) The elements of the application, if applicable, should appear in the following order:

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- (1) Utility Application Transmittal Form.
- (2) Fee Transmittal Form.
- (3) Title of the invention; or an introductory portion stating the name, citizenship, and residence of the applicant, and the title of the invention.
- (4) Cross-reference to related applications.
- (5) Statement regarding federally sponsored research or development.
- (6) Reference to a A Microfiche appendix. (See 37 C.F.R. 1.96 (c)). The total number of microfiche and total number of frames should be specified.
- (7) Background of the invention.
- (8) Brief summary of the invention.
- (9) Brief description of the several views of the drawing.
- (10) Detailed description of the invention.
- (11) Claim or claims.
- (12) Abstract of the Disclosure.
- (13) Drawings.
- (14) Executed oath or declaration.
- (15) Sequence Listing (See 37 C.F.R. 1.821 through 1.825).

(b) The elements set forth in paragraphs (a)(3) through (a)(5), (a)(7) through (a)(12) and (a)(15) of this section should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase A Not Applicable should follow the section heading. [43 FR 20464, May 11, 1978; 46 FR 2612, Jan. 12, 1981; paras. (h) and (i), 48 FR 2712, Jan. 20, 1983, effective Feb. 27, 1983; revised, 61 FR 42790, Aug. 19, 1996, effective Sept. 23, 1996].

Correction is required.

7) The drawings in the instant application do not comply with 37 C.F.R. § 1.821(d), which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. M.P.E.P. 2422.02 expressly states that "when a sequence is presented in a drawing,

regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings".

Correction is required.

8) The instant specification does not comply with 37 C.F.R. § 1.84(U)(1), which states that partial views of a drawing which are intended to form one complete view, whether contained on one or several sheets, must be identified by the same number followed by a capital letter. Figure 1 of the instant application, for example, is presented on three separate panels. The three sheets of drawings which are labeled "Figure 1" in the instant specification should be renumbered "Figures 1A, 1B and 1C". Applicant is reminded that once the drawings are changed to meet the separate numbering requirement of 37 C.F.R. § 1.84(U)(1), Applicant is required to file an amendment to change the Brief Description of the Drawings and the rest of the specification accordingly.

9) Claim 5 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 2. Claim 2 is limited to an encodable aromatic amino acid and claim 5 recites all encodable aromatic amino acids. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

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10) Claims 21 to 23, 34, 35 and 37 are objected to as reciting an improper Markush Group. M.P.E.P. 803.02 states that:

"Since the decisions in *In re Weber* \*\*, 198 USPQ 328 (CCPA 1978); and *In re Haas*, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention, *In re Harnish* , 631 F.2d 716, 206 USPQ 300 (CCPA 1980); *Ex Parte Hozumi* , 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility."

A nucleic acid, a polypeptide and an antibody thereto lack unity of invention because they lack a common utility that is based upon a common distinguishing structural feature or combination of features. In fact, these three compounds are structurally unrelated.

11) Claims 2, 6 to 8, 10 to 14 and 17 are allowable as written.

12) Claims to:

38. A nucleic acid molecule encoding an AMPA type glutamate receptor subunit that functions as a non-desensitizing AMPA-receptor subunit, wherein a leucine corresponding to the leucine at position 497 of SEQ ID NO:1 is replaced by an aromatic amino acid in the amino acid sequence of said subunit"

39. The nucleic acid molecule of claim 38 which is

(a) a nucleic acid molecule comprising a nucleotide sequence encoding a polypeptide having the amino acid sequence of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 9, or SEQ ID NO: 10, wherein the leucine residue corresponding to position 497 of SEQ ID NO: 1, 5 or 9, position 504 of SEQ ID NO: 2, 6 or 10, position 507 of SEQ ID NO: 3, position 505 of SEQ ID NO: 4 or 8, or position 513 of SEQ ID NO:7 is replaced by an aromatic amino acid;

or

(b) a nucleic acid molecule comprising a nucleic acid molecule having the nucleotide

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sequence of SEQ ID NO: 11, SEQ ID NO: 12, SEQ ID NO: 13, SEQ ID NO: 14, SEQ ID NO: 15, SEQ ID NO: 16, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19 or SEQ ID NO: 20, wherein the codon represented by nnn is a codon encoding an aromatic amino acid.

Would be allowable if submitted.

13) Claims 9, 15, 16, 22, 23, 34 and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. These claims encompass subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 9, 15 and 16 encompass a transgenic multicellular organism and a vector for the production thereof. The instant specification does not describe, in detail, a transgenic multicellular organism comprising a nucleic acid of the instant invention nor does it provide the guidance needed to produce such an organism. The production of a transgenic multicellular organism comprising a heterologous nucleic acid of interest was not a routine practice in the art at the time of the instant invention, as evidenced by the lack of a description, in either the instant specification or the art of record, of the successful production of even a single example of a transgenic multicellular organism comprising a heterologous nucleic acid encoding an ionotropic receptor like those described in the instant specification.

In a similar fashion, claims 9, 22, 23, 34 and 35 are drawn to a method of treatment by administering a nucleic acid encoding an ionotropic receptor subunit, and a vector or composition formulated specifically for this purpose. Again, there is not a single example presented in the specification or the art of record of the successful

administration of such a nucleic acid for clinical effect. One of ordinary skill would not reasonably expect the exogenous administration of a nucleic acid encoding all or part of a subunit protein of the instant invention to a mammal to have a clinical effect because the art of gene therapy has not developed to the level of a routine practice in the clinical arts. It is noted that several genetic defects associated with diseases such as sickle cell anemia and cystic fibrosis are well known in the art, as are the genetic corrections needed to cure these diseases, and yet these diseases have not been successfully treated by gene therapy. A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentec, Inc. v. Novo Nordisk*, 42 USPQ 2d 100,(CAFC 1997), the court held that:

“[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable” and that “[t]ossing out the mere germ of an idea does not constitute enabling disclosure”. The court further stated that “when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art”, “[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement”.

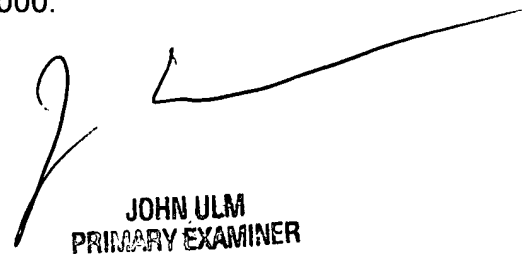
The instant specification is not enabling because one can not following the guidance presented therein and produce and use the claimed pharmaceutical without first making a substantial inventive contribution.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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